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ATORVASTATIN BUT NOT PITAVASTATIN SIGNIFICANTLY INCREASES FASTING PLASMA GLUCOSE IN PATIENTS WITH TYPE 2 DIABETES AND COMBINED DYSLIPIDEMIA

ACC Poster Contributions
Ernest N. Morial Convention Center, Hall F
Monday, April 04, 2011, 3:30 p.m.-4:45 p.m.

Session Title: Unique Trends in Hyperlipidemia
Abstract Category: 15. Pharmacology/Hormones/Lipids–Clinical
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Background: Several studies have reported deterioration of glucose metabolism following administration of statins. In Phase 3 clinical trials, pitavastatin (PITA) 2 and 4 mg were not statistically different on LDL-C reduction compared to atorvastatin (ATOR) 10 and 20 mg, respectively. This retrospective analysis examined fasting plasma glucose (FPG) changes with these two statins in patients with type 2 diabetes mellitus (T2DM) and combined dyslipidemia in a multinational Phase 3 trial (NK-104-305).

Methods: In this analysis of a 12-week, randomized, multicenter, double-blind trial of PITA 4 mg vs. ATOR 20 mg in patients with T2DM and combined dyslipidemia, we assessed mean changes in FPG levels from baseline to end of 12 weeks within each treatment (PITA, n=269, and ATOR, n=132) using paired t-test and between treatments using a general linear model, adjusting for study site, baseline glucose level, duration of diabetes, age, BMI, gender, insulin, diuretic and ß-blocker use at randomization.

Results: No significant changes in FPG were noted after 12 weeks of therapy with PITA when compared with baseline (mean change 2.6 mg/dL, p=0.1033) while significant increases in FPG were observed for ATOR (9.2 mg/dL, p=0.0062). A significantly greater change in FBG was observed in patients treated with ATOR than PITA (p=0.0081), particularly in women with T2DM (17.0 mg/dL [n=57] for ATOR vs. 3.5 mg/dL [n=117] for PITA, p=0.0071) as compared to men (3.2 mg/dL [n=75] for ATOR vs. 2.0 mg/dL [n=152] for PITA, p=0.3872). Sensitivity analyses after excluding patients who changed diabetic medication or were hospitalized during the study further supported the above findings.

Conclusions: No significant changes in FPG were noted after 12 weeks of therapy with pitavastatin 4 mg, while atorvastatin 20 mg significantly increased fasting plasma glucose in patients with T2DM and combined dyslipidemia. Due to the limitations of a post hoc analysis, further studies are needed to confirm the findings and their relevance to clinical outcomes.